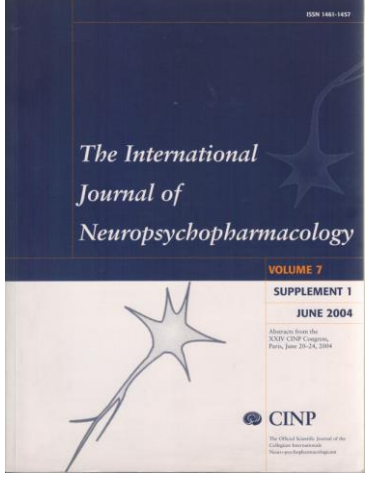

ESCITALOPRAM IN THE TREATMENT OF MAYOR DEPRESSION DISORDER WITH ANXIETY IN A ROUTINE CLINICAL OUTPATIENT CLINIC

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ABSTRACT

Background:
Escitalopram is a single isomer SSRI antidepressant that has been shown in clinical trials to improve depression symptoms associated with anxiety, panic and social anxiety disorders. This study was designed to evaluate the efficacy and tolerability of Escitalopram in the treatment of depression with or without anxiety symptoms in routine clinical outpatient clinic (Moizeszowicz, 1998).

Method:
Male and female outpatients aged 18 years and older who met DSM-IV criteria for Mayor Depression Disorder with baseline scores of 22, or greater, on Montgomery-Åsberg Depression Scale (MADRS) were assigned to treatment with Escitalopram (10-20 mg/day) extended 12 weeks, preceded of 1-week of washout period of another medications. The primary efficacy variable was the 50% mean change (*response*), or normal score (*remission*) (Frank *et al.*, 1991; Montgomery *et al.*, 1979), from baseline in total MADRS score at week 12. Other efficacy measures included changes in Hamilton Anxiety Scale (HAM-A), Clinical Global Impression Scale (Severity and Improvement, CGI-S, CGI,I) and Adverse Effects Scale (UKU); the subscales of apparent sadness, inner tension, reduced sleep or appetite and suicidal though, in the MADRS and psychic anxiety and somatic anxiety, in the HAM-A.

Results:
A total of 33 patients received treatment with Escitalopram. The sample represents patients of the daily clinic in contrast to classical investigation protocols.
The primary efficacy recovery (50% mean change in the MADRS score), was obteined in 20% of the patients at week 1 and, 40% at the week 2. Normal score from baseline in the total MADRS rating (*remission*), was obtained in 64% of the patients at week 4, 79% at week 8 and 88% at week 12. Escitalopram was very well tolerated. Of the 7 patients dropouts, only 2 were attributable to the antidepressant drug.

Conclusion:
Escitalopram is effective, save and well tolerated in the treatment of patients with MDD with or without anxiety symptoms.

INTRODUCTION

Escitalopram is a single-isomer SSRI antidepressant that has been show to significantly improve depression symptoms associated with anxiety, panic and social anxiety disorder (Davidson *et al.*, 2002).

Escitalopram and R-Citalopram together comprise Citalopram. However Escitalopram is the therapeutically active component. Recently, R-Citalopram has been shown to attenuate the SSRI-activity of Escitalopram.

Clinical trials comparing Escitalopram in treating depression, shown to be more effective and possibly better tolerated, than Citalopram (Burke *et al.*, 2002; Gorman *et al.*, 2002; Montgomery *et al.*, 2001; Owens *et al.*, 2002).

These considerations motivated the present examination of the safety and efficacy of Escitalopram in the treatment of Mayor Depression Disorder with or without symptoms of anxiety in a routine clinical outpatient practice in Buenos Aires, Argentina.

METHODS

STUDY DESIGN
- One-week wash out period followed by 12 weeks of treatment with Escitalopram.
- Escitalopram dose 10-20 mg/day for 12 week, flexibly dosed.

PRINCIPAL ENTRANCE CRITERIA
- Fullfilled DSM-IV criteria for current episode of mayor depression disorder.
- Montgomery-Åsberg Rating Scale for Depression (MADRS) ≥ 22.
- Hamilton Anxiety Scale (HAM-A) score ≥ 15.
- Clinical Global Impression of Severity (CGI-S) and Improvement (CGI-I).
- Male or female outpatient 18-80 years of age.

EFFICACY ASSESSMENTS
- Study measurements were made at screening (0) and 1, 2, 4, 8 and 12 weeks after starting treatment.
- MADRS were made at baseline and at weeks 1, 2, 4, 8 and 12.
  The pre-defined primary measure of antidepressant efficacy was the change from baseline of MADRS total score. Additional analyses efficacy included ***responders*** (proportion of patients at least 50% reduction of baseline MADRS total score/visit) and complete ***remitters*** (proportion of patients with MADRS total score ≥ 12 per visit).
- HAM-A psychic anxiety and somatic anxiety subscales.
- Clinical Global Impression Scale (CGI-Severity) was made at week 0, 1, 2, 4, 8 and 12. CGI-Improvement was made at week 1, 2, 4, 8 and 12.
- Safety was evaluated on the basis of adverse events.
- Adverse Effects Scale (UKU).

STATISTICAL ANALYSIS
The data were analyzed in a database (type Excel) with a microprocessor Amrad 750 Mhz (Statistica v.5, Statsoft Inc. 1997).
The appropriate descriptive statistics were determined for each variable according to their mensuration scale and distribution.
They were carried out the following calculations: percentages, accumulated percentages, confidence intervals for percentages (Odds ratio).
When necessary was carried out the following statistical tests: Fisher, t-test of Student, Wilcoxon, Kolmogorov-Smirnov, ANOVA of Kruskall Wallis, Friedman and for repeated measures.